K002242

SEP 2 0 2000

ODIN Technologies Ltd.
P.O. Box 248, Yokneam Elit 20698, Israel. Tel. 972-4-9591010, Fax. 972-4-9591011

510(k) Summary of Safety and Effectiveness

The Following 510(k) Summary of Safety and Effectiveness has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR § 807.92(a).

807.92(a)(1) - Submitter Details:

Submitter name:	Adi Ickowicz – Regulatory Affairs / Quality Assurance Director
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Contact Person:	Adi Ickowicz – Regulatory Affairs / Quality Assurance Director
Date:	July 19, 2000

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807.92(a)(2) - Device Details:

Trade Name and Common Name:	PoleStar N-10 - Magnetic Resonance Diagnostic Device
Classification:	21 CRF 892.1000 Magnetic Resonance Diagnostic Device.
Class:	II MRDD were reclassified by FDA from Class III to Class II effective July 28, 1998.
Product Code:	LNH – Magnetic Resonance Imaging System

807.92(a)(3) – Predicate Devices:

The PoleStar N-10 is comparable to Odin's NORMA 10 which was cleared on June 18, 1999.

Medical Device Name	Applicant Name	510(k) Number	Classification
NORMA 10	Odin Thechnologies Ltd.	K991243	Class II device

Additional Substantial Equivalence Information is provided in the attached Substantial Equivalence Comparison Table.

807.92(a)(4) – Device Description:

Device Functions:

The PoleStar N-10 utilizes a permanent magnet to acquire 2D single-slice, multi slice, and 3d volume images. A wide variety of pulse sequences are provided to the operator, including spin echo, gradient echo, fast spin echo, and steady state free precession acquisitions. The PoleStar N-10 is a widely open and compact Intraoperative MRI unit intended to be used in a typical pre-existing operating room. The PoleStar N-10 can be moved within the room between procedures, from the operating table to its Magnet Storage Cabinet, thus allowing the operating room to be used for any type of surgery.

Scientific Concepts:

Magnetic Resonance (MR) is based on the fact that certain anatomic nuclei have electromagnetic properties, which cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nucleus used in current imaging experiments in magnetic resonance. When placed in a magnetic field, there is a slight net orientation or alignment of these atomic nuclei with the magnetic field. The introduction of a short burst of Radiofrequency (RF) excitation of wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a reorientation of the proton's magnetization vector. When the RF excitation is removed, the proton relaxes and returns to its original orientation. The rate of relaxation is exponential, and varies with the character of the proton and its adjacent molecular environment. This reorientation process is characterized by two exponential relaxation times called TI and T2, which can be measured.

These relaxation events are accompanied by an RF emission or echo which can be measured and used to develop a representation of the emissions on a three dimensional matrix. Spatial localization is encoded into the echo by varying the RF excitation and by appropriately applying magnetic field gradients in x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of NMR characteristics of the nuclei under consideration can he constructed by using image processing techniques similar to those used in CT.

For magnetic fields up to 1.5T, the RF frequencies commonly used range up to 65MHz. The RF fields have pulsed power from several watts to greater than 2 kilowatts, and repeat at rates from once every few seconds to greater than fifty per second. The time-varying magnetic gradient fields have a typical duration of sub-millisecond to several milliseconds.

Physical and Performance Characteristics:

ODIN Technologies Ltd., has developed an open MRI system based on an innovatively designed permanent magnet of 0.12 Tesla. The system is compact, displaceable, inexpensive, and widely open.

The magnetic probe consists of two lateral permanent-magnet poles that can be adjusted laterally and longitudinally, mounted on a C-arm gantry. The anatomic region to be scanned is positioned between the poles. Except for the anatomic region being scanned, the patient is positioned outside of the gantry, thus enhancing patient comfort and reducing the possibility of a claustrophobic reaction.

807.92(a)(5) – Device Intended Use:

The general purpose of the device as defined in 21 CFR 892.1000:

The PoleStar N-10 is a Magnetic Resonance Diagnostic Device intended to produce transverse, sagittal, coronal, and oblique 2D and 3D images of the extremities and selected sections of the head. The images produced by the PoleStar N-10 reflect the spatial distribution of protons (Hydrogen Nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and T2*.

- Anatomical regions: extremities and selected sections of the head.
- Nuclei excited: H-1
- Diagnostic uses: T1, T2, T2* and density weighted imaging.

The PoleStar N-10 is intended to be used intraoperatively in a standard operating room. When interpreted by trained physicians, the MR images provide information that can be useful in determining a diagnosis.

807.92(a)(6) – Substantial Equivalence Comparison Table:

Model / parameter	Odin PoleStar N-10	Odin NORMA 10
Clinical application	Extremities and selected sections of the head	Extremities and selected sections of the head
Magnet type	Permanent	Permanent
Field strength	0.12T	0.12T
5 gauss fringe field (radial/axial, m)	1.5	1.5
Shimming	Passive, active	Passive, active
Gradient subsystem		
Strength mT/m	25	25
Rise time to 10mT/m	<1	<1
msec		
Computer system		
- CPU:	Pentium 586	Pentium 586
- Memory size [MB]	64	64
array processor	4xDSP C44 TI	4xDSP C44 TI
- Memory size [MB]	4000	4000
storage media	magnetic disk, floppy disk	magnetic disk, floppy disk
number of images stored	5000	5000

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Model / parameter	Odin PoleStar N-10	Odin NORMA 10
Imaging modes:		
- single	Yes	Yes
- multislice	Yes	Yes
- volume study	Yes	Yes
- other	FSE, Multislice	FSE, Multislice
Reconstruction time:		
- single slice, sec	<3/slice	<3/slice
- multislice, sec	<3/slice	<3/slice
- volume sec	<20/slice, ave.	<20/slice, ave.
Cardiac gating (ECG/peripheral)	No	No
Respiratory gating	No	No
Angiography	Optional	Optional
Spectroscopy	No	No
Imaging;		
- pulse sequence	Spin Echo, Fast Spin Echo, Gradient Echo, 2D 3D	Spin Echo, Fast Spin Echo, Gradient Echo, 2D 3D
- repetition time, msec	50-5000 increments of 1	50-5000 increments of 1
- echo time, msec	5-150	5-150
- inversion time, msec	N/A	N/A
- slice thickness, mm	4-10	4-10
- FOV, cm	5-18	5-18

Model / parameter	Odin PoleStar N-10	Odin NORMA 10
- scan orientation	Transverse, coronal, sagittal, oblique	Transverse, coronal, sagittal, oblique
- measuring matrix	64x64 to 256x256 steps of 1 in phase encoding	64x64 to 256x256 steps of 1 in phase encoding
- display matrix	1024x768	1024x768
- pixel intensity	0-4095	0-4095
Surface coils:		
- spine	No	No
- knee	Yes	Yes
- neck	No	No
- TMJ	No	No
- extremity	Yes	Yes
- head	Yes	Yes
- breast	No	No
- shoulder	No	No
- others	No	No
Bore diameter or WxH, cm	24.5x39	24.5x39

Model / parameter	Odin PoleStar N-10	Odin NORMA 10
Bore features	Open access to patient	Open access to patient
Cooling system type	Water cooling (Gradients only)	Water cooling (Gradients only)
Cryogen use	NA	NA
Magnet weight, kg	380	380
HxWxD, cm	135x86x80	135x86x80
Dicom 3.0 interface	No	No
Power requirements: - line voltage, V - Kva - A/C, BTU/hr	 3x208 (3 phase) 16 <10000	 3x208 (3 phase) 16 <10000

Clinical Data:

Clinical testing of the system during surgery was performed in the United States and in Israel, during the period of October 1999 through July 2000.

Conclusions from Testing:

Based on the clinical testing the following conclusions can be drawn:

- The device can be utilized in a safe and efficatious manner in the operating room.
- The device does not alter the normal operating room workflow and does not cause changes in existing procedures.
- Versitale use of the operating room, when the system is stored in the Magnet Storage Cabinet the operating room can be used for any type of procedure.

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807.92(d) – Other information required by the FDA:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2000

Adi Ickowicz
Regulatory Affairs/Quality Assurance Director
Odin Technologies, Ltd.
P.O. Box 248
Yokneam Elit
Israel

Re: K002242
PoleStar N-10 (MRI System)
Dated: July 19, 2000
Received: July 24, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Ickowicz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K00 2242

Device Name: **PoleStar N-10**

Indication For Use:

The PoleStar N-10 is a Magnetic Resonance Diagnostic Device intended to produce transverse, sagittal, coronal, and oblique 2D and 3D images of the extremities and selected sections of the head. The images produced by the PoleStar N-10 reflect the spatial distribution of protons (Hydrogen Nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and T2*.

Anatomical regions: extremities and selected sections of the head.

Nuclei excited: **H-1**

Diagnostic uses: **T1, T2, T2* and density weighted imaging.**

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(PLEASE DO NOT WRITE BELOW THE LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002242